

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION NO. 09-0366 (FSH)

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BOEHRINGER INGELHEIM INTERNATIONAL, :
GMBH and BOEHRINGER INGELHEIM : TRANSCRIPT
PHARMACEUTICALS, INC., :
Plaintiffs, : OF
-v- : PROCEEDINGS
:
MYLAN PHARMACUETICALS, INC., and :
MYLAN, INC., :
:
Defendants. :
- - - - - x

May 12, 2009
Newark, New Jersey

B E F O R E: HONORABLE FAITH S. HOCHBERG, U.S.D.J.

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following transcript is certified to be an accurate record
taken stenographically in the above entitled proceedings.

s/ John K. Stone

JOHN KEVIN STONE,
Official Court Reporter

1 THE CLERK: The Court calls Boehringer versus
2 Mylan.

3 THE COURT: Good afternoon.
4 Just identify who will be arguing for each side,
5 whoever is arguing.

6 MR. WEXLER: Bruce Wexler from Paul Hastings for
7 the plaintiffs.

8 THE COURT: Bruce Wexler. Okay.
9 You'll be doing the argument today?

10 MR. WEXLER: Yes, for the plaintiffs.

11 THE COURT: Okay.
12 You want to introduce your colleagues?

13 MR. WEXLER: Bill Heller from McCarter, and Eric
14 Dittmann, colleague of mine in Paul Hastings.

15 THE COURT: All right.
16 And who will be arguing for the defendant?

17 MS. BLOODWORTH: I will, Your Honor.
18 Shannon Bloodworth from Perkins Coie.

19 THE COURT: Okay.
20 Do you want to introduce --

21 MS. BLOODWORTH: Yes. Mr. David Harth from Perkins
22 Coie and Arnold Calmann from Saiber.

23 MR. CALMANN: Afternoon, Your Honor.

24 THE COURT: Okay.
25 Everyone can be seated.

1 I actually brought these down from the Judges'
2 lunch today, so you get them if you work something out that
3 makes sense here. They're the courtesy of all the Judges,
4 since we all jointly chip in for them.

5 All right. This is your chance to be heard both on
6 the application for a stay and on the motion to dismiss. I
7 have not yet decided whether I will in fact decide the
8 motion to dismiss or not. And I say that because, having
9 discussed this with Judge Shwartz, and having read the
10 papers, one of the questions that comes to mind, as I
11 understand how you've all graciously decided in the interest
12 of judicial economy you should not do discovery but in the
13 interest of judicial economy I should write an opinion that
14 may not ever need to be written. And I, as Judge Shwartz
15 said, I asked them 10 times how does that make sense. So
16 that's one of the questions.

17 But getting beyond that, I have a series of other
18 questions. So first, let's start.

19 Has everybody -- can everybody verify they've done
20 all the possible research on the motion to dismiss in all
21 the various permutations in which this case may arise? Has
22 everybody done it so nobody's going to ask me for more
23 briefing today?

24 MS. BLOODWORTH: That's correct, Your Honor.

25 MR. WEXLER: No, Your Honor, we won't ask for more

1 briefing.

2 THE COURT: Okay. Fair enough.

3 Second question of course is, what is the current
4 status of the matter pending before the Federal Circuit?

5 MR. WEXLER: Your Honor, oral argument has been
6 scheduled for June 1st, which is less than three weeks from
7 now.

8 We have some other information that we wanted to
9 talk through today, we thought might be helpful to Your
10 Honor, in lieu of further briefing.

11 But I assume we'll get to that later. But I'm
12 happy to raise that now if Your Honor would prefer.

13 THE COURT: Well, if you want to say something, now
14 is your chance to say it. So please do.

15 MR. WEXLER: Okay.

16 Well, in terms of the Federal Circuit appeal, in
17 terms of the first action, the first action involved a claim
18 on a first ANDA for a drug product by Mylan.

19 THE COURT: Wait a minute. Is this your oral
20 argument or is this -- are you just bringing the additional
21 information --

22 MR. WEXLER: There's some additional information
23 weaved through that I needed to raise with Your Honor today
24 that I wanted to talk through --

25 THE COURT: So is this in terms of scheduling and

1 what may happen in the various permutations in the Federal
2 Circuit, is that what this is?

3 MR. WEXLER: Yes.

4 THE COURT: Okay. Fair enough.
5 Proceed.

6 MR. WEXLER: So in other words, the first action
7 -- should I --

8 THE COURT: You can be anywhere you'll be
9 comfortable. The microphones will pick you up wherever you
10 are.

11 MR. WEXLER: Wherever, what Your Honor --

12 THE COURT: Doesn't make a difference.

13 MR. WEXLER: Okay.

14 So in the first action the plaintiffs sued Mylan on
15 a patent for a particular ANDA product.

16 THE COURT: Correct.

17 MR. WEXLER: So that action was decided on double
18 patenting grounds. That is now on appeal at the Federal
19 Circuit.

20 THE COURT: I've read all the papers, every single
21 word.

22 MR. WEXLER: All right. Okay.

23 So where I'm going with this, we were asked by
24 Judge Shwartz a couple of questions, and following those
25 questions there's two, I think at least two pieces of

1 information I'd like to bring to your attention.

2 One is what we already brought to Judge Shwartz'
3 attention, but I'm not sure if it's of record here, which is
4 the median time to disposition.

5 The Federal Circuit publishes statistics, we were
6 asked if we had any data on that. The Federal Circuit on
7 their website at cfac.us.gov publishes statistics, and I
8 have a copy of the web page that we covered at the hearing
9 with Judge Shwartz, that shows that the median time to
10 disposition is approximately 12 months from docket.

11 Now, the appeal was docketed at the end of October
12 '08. So if you calculate 12 months from October '08, that
13 lands you right about October of '09, which would be the
14 median time to disposition by the Federal Circuit.

15 THE COURT: Hhmm-hmm.

16 MR. WEXLER: So the two pieces of data we have are
17 June 1, oral argument, and a median time disposition of
18 October 2009.

19 THE COURT: Fair enough.

20 When I sat with them, they expect draft opinions
21 within 90 days, and ideally within 60. And they stick to
22 it. It's a very prompt circuit.

23 MR. WEXLER: And the other piece of information
24 that I have for Your Honor, is that we were asked a question
25 by Judge Shwartz, what would the case look like, in other

1 words, if the Federal Circuit affirms, then obviously the
2 affirmance means the patent is valid on de novo review, the
3 case is essentially over here.

4 THE COURT: Is not essentially -- well, I have
5 various questions of my own.

6 MR. WEXLER: All right.

7 THE COURT: So if they affirm --

8 MR. WEXLER: Yes.

9 THE COURT: -- this case is completely over.
10 Everyone agrees on that?

11 MR. WEXLER: Yes.

12 MS. BLOODWORTH: Yes, Your Honor.

13 THE COURT: Okay.

14 If they reverse, can you both assert that there
15 will be no further discovery necessary to be done in this
16 case?

17 MR. WEXLER: And in our view, and this is what I
18 wanted to raise with Your Honor, after we were asked that
19 question I went back and looked at some of the case law that
20 existed on that -- that scenario, what would happen if the
21 Federal Circuit reverses and finds that there is no double
22 patenting on de novo review, what would the case look like.

23 There is a case that I found, a Federal Circuit
24 opinion, that looks just like what this case would look
25 like. And I thought it would be interesting to show Your

1 Honor a copy of the case.

2 I'll give it to opposing counsel. I -- it's just
3 basically additional authority, legal authority, that might
4 be of interest to Your Honor.

5 MS. BLOODWORTH: Your Honor, in our opinion this
6 case was over when the Delaware court obviously ruled the
7 patent was invalid. And if this case is reversed, in our
8 opinion, that puts the ball back in Boehringer's court, and
9 we really feel like the place for that, for this case is to
10 be back in Delaware in front of Judge Farren.

11 THE COURT: And we'll get there. That's one of the
12 permutations we'll get to. And I'm inclined to agree with
13 that. But I wanted to give everybody a chance to be heard.

14 MR. WEXLER: And so in the Roche v. Apotex case, if
15 I may hand it up to Your Honor --

16 THE COURT: Yes, you may.

17 MS. BLOODWORTH: And Your Honor, it was cited in
18 our case --

19 THE COURT: There's so many certifications. It's
20 hard to keep track of them all.

21 MR. WEXLER: Two sets of collated --

22 THE COURT: All right.

23 So I'm still waiting for an answer to my question.
24 The pending question is --

25 MR. WEXLER: So -- yes.

1 THE COURT: -- the pending question is, I just
2 want to be sure you remember the question and you're
3 answering.

4 MR. WEXLER: The question is what will the case
5 look like if the Federal Circuit reverses.

6 THE COURT: No, the question is, can you both
7 assert to me that if the Federal Circuit reverses there's no
8 need for any further discovery here?

9 MR. WEXLER: And our position is that there
10 shouldn't be, and there isn't, and the Roche -- Roche v.
11 Apotex -- Apotex case, in a section where you get a second
12 ANDA --

13 THE COURT: I'm not about to rule on it. Your
14 position is there will be no need for further discovery.
15 And your position?

16 MS. BLOODWORTH: Our position is it -- depending
17 upon the ruling from the Federal Circuit, and its
18 parameters, there may be a need for a limited amount of
19 additional discovery, based on Boehringer's later filing of
20 the terminal disclaimer, which was not part of the Delaware
21 action.

22 They filed a terminal disclaimer after the close of
23 evidence at the trial. That issue is currently up on appeal
24 before the Federal Circuit. So again, until I understand
25 the contours of the Federal Circuit's exact reversal, we may

1 need to make some adjustments to at that time.

2 THE COURT: Can you anticipate, is that the only
3 open issue? Is it possible to do that discovery now or are
4 you saying that that --

5 MS. BLOODWORTH: It would be possible to do that
6 discovery now, Your Honor. We would argue that that's very
7 burdensome, to put Mylan to the cost of that discovery on a
8 speculative decision by the Federal Circuit.

9 THE COURT: Believe me, I share your sympathies,
10 but you're asking me to decide a case.

11 MS. BLOODWORTH: Yes.

12 THE COURT: I mean you have a whole -- you both
13 have hundreds of lawyers to help you. I've got two.

14 MS. BLOODWORTH: And our case, Your Honor, is quite
15 simply that we moved to dismiss so that we didn't have to be
16 subjected to such costly discovery.

17 THE COURT: I understand that.

18 But understand that judicial economy usually means
19 less work for courts.

20 MS. BLOODWORTH: Again, we believe --

21 THE COURT: Not less discovery for clients.

22 MS. BLOODWORTH: -- and the best place for such
23 discovery would be back in front of Judge Farren in the
24 District of Delaware.

25 THE COURT: Well, how about a ruling or an

1 agreement that says if there is a reversal, both sides agree
2 to transfer this case to Delaware where there would be an
3 open case to take it? Is there any impediment? Is venue
4 good in Delaware?

5 MS. BLOODWORTH: We would be fine with that, Your
6 Honor.

7 THE COURT: Is venue okay in Delaware?

8 MR. WEXLER: Yes.

9 THE COURT: Okay. So that the only -- is that kind
10 of agreement forgivable?

11 MR. WEXLER: I think so, Your Honor.

12 The only caveat is if there's an outright reversal,
13 in our view the case is done in our favor. So the only
14 contingency would be in some unusual situation --

15 THE COURT: In other words, if there's a reversal
16 and no remand --

17 MR. WEXLER: That's correct.

18 THE COURT: But you could still agree to transfer
19 it to him or her. Is it a him?

20 MS. BLOODWORTH: Yes, Your Honor.

21 THE COURT: He could decide whether or not that's
22 true, having had a full hearing on the same patent.

23 MR. WEXLER: Yes, Your Honor.

24 I mean either way is fine with us.

25 In other words, if the court, Federal Circuit

1 reverses, and directs that judgment be entered in our favor,
2 it's ministerial whether this court enters it or Delaware.
3 So if there's a transfer, it may just be easier --

4 THE COURT: But she may not agree with you.

5 MR. WEXLER: Right.

6 THE COURT: So -- about whether it's ministerial to
7 end it.

8 But you -- so I'm hearing that you're willing to
9 agree that if there is a reversal by the Federal Circuit,
10 you're both in agreement that this case, in that event,
11 should be transferred to Delaware.

12 MS. BLOODWORTH: Yes, Your Honor.

13 MR. WEXLER: We would be willing to do that, yes,
14 Your Honor.

15 THE COURT: Okay. All right.

16 So then -- and that there would only be a very
17 limited amount of discovery. About how long?

18 MS. BLOODWORTH: Your Honor, I --

19 THE COURT: You can't because you can't -- the last
20 time anybody -- the reason for my questioning is, you may or
21 may not have been involved in patent law at the time, it was
22 some number of years ago, I had -- I was new on the bench,
23 and I had a group of seasoned patent lawyers come to me and
24 say, you know, you need to stay Fuji versus Jazz, because
25 the issue's going to the Federal Circuit, and it's going to

1 decide all the issues, and it may obviate the need for a
2 case at all. And even if it doesn't, it will be so clear
3 what's going to happen, we'll probably be able to meet
4 immediately and settle and it will be all over.

5 So I fell for it. Huge mistake. Three years
6 later, Fuji versus Jazz comes down, nobody agrees that it
7 disposes of the case, or even -- they can't even agree on
8 what it means. And so we -- and discovery has not started.

9 So they did agree that they would be bound by the
10 discovery in the Court of International Trade, which was the
11 case that was up to the Federal Circuit. They said they
12 presented the same issue as Fuji versus Jazz, they agreed to
13 that, so I said, fine, your discovery is done, so let's get
14 going with this trial.

15 It was going to be a long trial. In fact, it was a
16 long trial. And along comes the Court of International --
17 no, one of the International Trade offices of the Government
18 says, no -- no, no, they aren't allowed to make that
19 agreement. Discovery has to start all over again. I said
20 no, they made that agreement. And it's a court order. And
21 so discovery is done. They're going to use the discovery
22 they used before the Court of International Trade. And
23 the -- whoever it was, the General Counsel of the
24 International Trade Commission attempted a mandamus petition
25 on that issue. Which then we had to wait for it to go up to

1 the circuit and get, you know, mandamus denied, and then we
2 could get started.

3 And all I'm saying is -- and then it was a three
4 month trial. So nothing was saved by the stay. Indeed, my
5 calendar was put into complete havoc by the stay. That's
6 my -- the reason for my rather exigible questions.

7 MR. WEXLER: And, Your Honor, I think that's the
8 co-pending application, I think I'm familiar with that case,
9 Fuji versus Jazz, but in this case --

10 THE COURT: There are many Fuji -- I mean Fuji and
11 Jazz have a long and tortured history.

12 MR. WEXLER: Yes.

13 But in this case, Your Honor, the issues on appeal
14 are discrete legal issues. So the reason for the exception
15 for collateral --

16 THE COURT: And they were too. So that's why --
17 they were repair or reconstruction, straight legal issues.
18 The circuit would just hand it down and it would be all
19 settled. Isn't what happened.

20 MR. WEXLER: And, Your Honor, what we haven't
21 really heard is an articulation of what kinds of discovery
22 would be had in the case on remand.

23 Because if I could, for just a second, the issue on
24 appeal is whether this terminal disclaimer obviated double
25 patenting. If the Federal Circuit rules that it did --

1 right, if the Federal Circuit rules it didn't, then it
2 affirms. If the Federal Circuit rules that it obviates
3 double patenting, moots it, then the case is over. There's
4 no need for discovery. Because the case is over.

5 Now, if the Federal Circuit rules that the second
6 issue on appeal, pure legal one, is whether a statute
7 protects Boehringer against a double patenting defense, 35
8 U.S.C. 121, if the Federal Circuit finds that the statute
9 does protect, then again there's no remand or need for
10 discovery. Because they've made a ruling on a statutory
11 interpretation.

12 And the last point, Your Honor, is in this Roche
13 case that I handed you, it holds that a defendant, a generic
14 defendant, in that case Apotex, who finishes a first case
15 and then there's a second case, they are barred by claim
16 preclusion after the appeal from raising any defense that
17 could have been raised in the first case. So it can't
18 possibly be the situation that we're going to hear a whole
19 bunch of new defenses in this case. And discovery --

20 THE COURT: You're using issue preclusion against
21 them, they're using issue preclusion against you.

22 MR. WEXLER: Right.

23 So what I'm saying is, the law is, because we have
24 a de novo issue on appeal, there's two pieces --

25 THE COURT: Don't be so strong on how you're going

1 to end that sentence. Why don't you rethink that sentence
2 in the interest of professionalism. Let's start again.

3 MR. WEXLER: Okay.

4 Because the issues are -- on appeal are purely de
5 novo issues, --

6 THE COURT: It's not a de novo trial. It's an
7 appeal of a legal issue that gets a de novo standard of
8 review.

9 MR. WEXLER: And, Your Honor, I understand it's not
10 a trial de novo.

11 THE COURT: That's the distinction. It's not a
12 trial de novo. So let's be clear on that.

13 And then finish your sentence about whatever the
14 law is. Because I didn't find clear law on that in either
15 side's brief, despite you taking the one District Court case
16 you had and pushing it to the limits that one could push it
17 or more.

18 MR. WEXLER: All right.

19 And I'd be happy to get into a discussion of the
20 law and try to go into more detail. I'm obviously doing an
21 abbreviated discussion here.

22 THE COURT: But -- no, no, say whatever you want.

23 MS. BLOODWORTH: And, Your Honor, we would like to
24 respond to some of these points as well.

25 THE COURT: You will.

1 MS. BLOODWORTH: As to the timing issues
2 especially. I can -- maybe I can address, since we seem to
3 be past those --

4 THE COURT: Yes. Let's -- fine.

5 MS. BLOODWORTH: So the patent expires in October
6 2010. So we will obviously not be here before Your Honor if
7 there is a stay, and we're obviously against any stay in
8 this issue, because there will be no more patent.

9 THE COURT: I thought you agreed to a stay?

10 MS. BLOODWORTH: We agreed to a stay of discovery
11 to prevent our client from going through the cost of
12 discovery while this motion to dismiss was pending.

13 THE COURT: Oh. I thought you agreed to a stay of
14 discovery until the circuit ruled?

15 MS. BLOODWORTH: No, Your Honor.

16 We agreed to a motion -- we agreed to stay
17 discovery while this motion to dismiss was pending. And
18 that was very clear in our correspondence.

19 And I understand that the order was maybe crafted,
20 you know, not exactly drafted quite clearly, but Mylan did
21 not agree to a stay of this action in toto. We agreed to a
22 stay to save ourselves the cost of --

23 THE COURT: Okay. Then that's -- we never do
24 things sort of one-handed like that. You either -- you
25 don't stay pending somebody else doing work. Okay?

1 Especially when that else is a court.

2 MS. BLOODWORTH: Right.

3 THE COURT: Which has far fewer resources to do
4 work than you do.

5 So you were either seeking a stay of everything or
6 a -- seeking a stay of nothing, including getting discovery
7 ongoing.

8 MS. BLOODWORTH: Mylan agreed to Boehringer's --
9 the parties agreed to stay discovery until this case, this
10 motion to dismiss was decided.

11 THE COURT: Okay.

12 MS. BLOODWORTH: And I didn't understand Your
13 Honor's --

14 THE COURT: I'm not saying I don't agree with you,
15 you don't control the Court's calendar, I do.

16 MS. BLOODWORTH: And -- right, Your Honor.

17 THE COURT: Okay. So that's off the table.

18 MS. BLOODWORTH: Right.

19 THE COURT: And so forget that agreement.

20 I'm not going to agree that both sides can get
21 together and decide, hey, we're going to save ourselves the
22 time, the work and money, but the court can keep going on
23 something that may be mooted by a Federal Circuit decision.
24 There's no way that's in the interest of judicial economy.

25 MS. BLOODWORTH: I understand, Your Honor, and I

1 completely agree.

2 THE COURT: All right.

3 MS. BLOODWORTH: And we were trying to save not
4 just yours, but Magistrate Shwartz, the problem and the time
5 and expense incurred in overseeing discovery in this action,
6 when in our minds the patent is invalid. Boehringer has
7 asserted no patent against us --

8 THE COURT: I understand that.

9 Magistrate Judge Shwartz is not in agreement
10 either, that basically everybody's stopping but the court --

11 MS. BLOODWORTH: Right.

12 THE COURT: -- is not in the interest of judicial
13 economy. I usually -- it's the other way around, the court
14 tries to not reach issues that it doesn't need to reach
15 unnecessarily.

16 MS. BLOODWORTH: In the interest --

17 THE COURT: If there's an issue one doesn't need to
18 reach in the interest of judicial economy, one doesn't reach
19 it. But it doesn't mean the parties don't keep going with
20 their cases. That's ordinarily how that concept and
21 doctrine works.

22 MS. BLOODWORTH: And our motion to dismiss was
23 officially -- only brought for judicial economy. We don't
24 see why there is patent litigation that is required in this
25 court at all. This patent is held invalid, so --

1 THE COURT: It's -- okay.

2 Let me ask you both this.

3 Do you both agree, as you stand here today,
4 regardless of what the circuit may do, if it rules tomorrow
5 or next week, and there's a -- whether it's an affirmance or
6 reversal, regardless of what it does, it doesn't affect the
7 legal issues of issue preclusion that you briefed?

8 MS. BLOODWORTH: That's correct, Your Honor.
9 That's Mylan's position.

10 MR. WEXLER: I don't understand that position, Your
11 Honor. The Federal Circuit's ruling, on their sole defense
12 that they took to trial, if the Federal Circuit reverses,
13 they're done. If the Federal Circuit affirms --

14 THE COURT: No, the issue is not what the -- what
15 the merits are, but the issue of issue preclusion. Does the
16 law of issue preclusion change at all based on what the
17 circuit does? That's my question.

18 MR. WEXLER: Yes.

19 MS. BLOODWORTH: No, Your Honor.

20 And the Court in Pharmacia v. Mylan addressed this
21 very question. It's briefed and it's cited in our briefs.
22 We'd like to provide a copy for you, but it's on all fours
23 for exactly -- this case is exactly like what is now in
24 front of Your Honor. There was a sister case where their
25 patent was found invalid and obvious, and the parties

1 brought another case in the District of Virginia against
2 Mylan. Mylan argued collateral estoppel. It went up to the
3 Federal Circuit and the Federal Circuit affirmed.

4 And in this case, the sister companion case, in
5 post-trial briefing, it hadn't actually been appealed yet,
6 the Federal Circuit said, very clearly, it's invalid, the
7 District Court's judgment of invalidity is fine for claim
8 preclusion purposes. It's to address very -- this very
9 situation that is occurring here today.

10 THE COURT: Okay.

11 Do you have a response on that case?

12 MR. WEXLER: Yes.

13 In the Pharmacia case, first of all, we heard a
14 piece of this, but in the Pharmacia case there was a finding
15 of invalidity for obviousness and network conduct. On the
16 appeal of that issue, it was highly fact intensive, and the
17 Federal Circuit was going to apply a very deferential
18 standard of review, and if you look at the appeal of the
19 Pharmacia decision, Upjohn v. Mobil, 225 Fed. 136-06, you
20 can see the appeal of that underlying decision that was
21 highly fact intensive. So it's different in that regard.

22 THE COURT: So wait a minute. Tell me your answer
23 to my question then.

24 MR. WEXLER: Which was that whether or not this is
25 on all fours, the answer is no.

1 THE COURT: What does the law -- give me a cite for
2 the proposition that the law of issue preclusion, whether
3 you're precluded from raising an issue again if you've
4 raised an issue in a previous case, whether issue -- the law
5 or doctrine of issue preclusion is affected by whether the
6 circuit reverses or affirms.

7 MR. WEXLER: Because the cite --

8 THE COURT: Is the answer yes or no?

9 MR. WEXLER: The issue preclusion, we submit, in
10 this case it attaches at the Federal Circuit ruling, not
11 before.

12 THE COURT: You're saying there's no issue
13 preclusion at all?

14 MR. WEXLER: Not at this time.

15 MS. BLOODWORTH: That's incorrect, Your Honor.

16 THE COURT: Okay.

17 What cite supports that?

18 MR. WEXLER: The Moore case.

19 Now, I know, Your Honor, obviously I agree with
20 Your Honor, this is not area of law -- it's an usual
21 situation where the appeal involves purely legal issues.
22 But the Moore case that we cited to Your Honor --

23 THE COURT: Is that the District Court case?

24 MR. WEXLER: The District Court case.

25 THE COURT: Do you have anything beyond Moore?

1 MR. WEXLER: The Federal Circuit hasn't addressed
2 one way or the other the question, if you have an appeal
3 that concerns de novo review, essentially a do-over on the
4 issues that the Federal Circuit is reviewing --

5 THE COURT: Stop calling it a do-over. It's not a
6 do-over.

7 Let's be straight on the terminology we use. I
8 understand the principle that you're raising, and I'm happy
9 to read any case you present to me.

10 But a de novo standard of review applied to a legal
11 determination by a District Judge is not a do-over of the
12 case in any way. It's basically applying a non-deferential
13 standard of review.

14 MS. BLOODWORTH: And, Your Honor, in the Pharmacia
15 case, that's exactly what was on appeal to the Federal
16 Circuit was an obvious de novo review.

17 THE COURT: I understand that.

18 But then the question is why not wait and send all
19 this, when there is a case in Delaware to receive it, or
20 even transfer it to Delaware without a case there?

21 MS. BLOODWORTH: Because while this action is
22 pending, what Boehringer has received is a 30 month stay of
23 Mylan's approval from the FDA.

24 THE COURT: They got a second 30 --

25 MS. BLOODWORTH: They got a second 30 month stay --

1 THE COURT: I thought it was --

2 MS. BLOODWORTH: -- because it's a .75 milligram
3 as opposed to the four which were --

4 THE COURT: When did the 30 month stay commence?

5 MS. BLOODWORTH: Upon Boehringer's suit --

6 THE COURT: Under the suit you got a second 30
7 month --

8 MR. WEXLER: Under the statute you get a second 30
9 month stay.

10 THE COURT: I understand that under Hatch-Waxman
11 you got a 30 month stay --

12 MR. WEXLER: The answer is yes.

13 MS. BLOODWORTH: Yes, Your Honor.

14 MR. WEXLER: Under the statute, there is a second
15 dosage, there's a second 30 month stay for that ANDA.

16 THE COURT: How can you -- why are you agreeing to
17 any kind of stay?

18 MS. BLOODWORTH: All we agreed to was a stay of
19 discovery so we wouldn't have to incur any additional
20 expense.

21 And I understand that was philosophically
22 incorrect, and we would take that back if we could. We want
23 this case to be dismissed. We are being highly prejudiced,
24 we have no ability to get final FDA approval while this case
25 is pending under Hatch-Waxman --

1 THE COURT: Why is that? What section --

2 MS. BLOODWORTH: 355(J)(5)(b)(4), Your Honor.

3 Because the case below, the Delaware action, in the Delaware
4 action, Boehringer was first filed, Boehringer has a 180 day
5 exclusivity on four of the strains of the product at issue.
6 Mylan has first to file exclusivity on the .75 milligram
7 product, which is at issue in this case.

8 THE COURT: Hmm-hmm.

9 MS. BLOODWORTH: Because Boehringer has 180 day
10 exclusivity, the patent cannot be delisted until that 180
11 day exclusivity period has run. So that when Mylan filed
12 its .75 ANDA, despite the fact that the patent had been held
13 invalid, we had to certify, with a paragraph 4 certificate
14 to the 812 patent. That triggered the 25 day window, and
15 they brought suit alleging infringement of the very same
16 patent that was already held to be invalid. And that's what
17 triggered another stay.

18 THE COURT: Why didn't you sue in Delaware?

19 MR. WEXLER: Because the purpose in this case --
20 first of all, I wasn't involved in the Delaware case, but
21 the main --

22 THE COURT: I don't mean you personally, why didn't
23 your client sue in Delaware?

24 MR. WEXLER: But because in this case what we were
25 really hoping to do was to see -- frame up the contentions

1 right away that would tee-up a summary judgment once we got
2 the Federal Circuit ruling. And this Court has the early
3 contention discovery which we set up with Judge Shwartz, a
4 schedule where we could do the contention discovery right up
5 front.

6 THE COURT: So you picked us because of our local
7 patent rules --

8 MR. WEXLER: Local patent rules were conducive to
9 either Court --

10 THE COURT: Was the Delaware court case still
11 pending wherein that 45 day window to bring the suit?

12 MR. WEXLER: No, the Delaware case was concluded,
13 we took the appeal and then the issue --

14 THE COURT: Is -- is Boehringer now marketing?

15 MR. WEXLER: No.

16 MS. BLOODWORTH: Boehringer -- we settled with
17 Boehringer under a marketing agreement, they would be
18 marketing as early as June 1, 2010.

19 MR. WEXLER: So Mylan --

20 THE COURT: Boehringer is marketing -- you entered,
21 basically entered into some financial arrangement with them
22 about the marketing?

23 MR. WEXLER: Boehringer is not marketing,
24 Boehringer is going --

25 THE COURT: Did you enter into a financial

1 agreement with Boehringer about when they would go to
2 market?

3 MR. WEXLER: The settlement agreement provides when
4 Boehringer could come into the market.

5 THE COURT: How much did you pay them?

6 MR. WEXLER: First of all, I wasn't involved, I
7 can't say that anything was paid to Boehringer.

8 THE COURT: Was anything paid?

9 MR. WEXLER: The answer is I don't know. And I'm
10 not about to -- I can't represent whether or not it was or
11 that it even was --

12 THE COURT: Is there anybody here that knows?

13 A VOICE: I'm the client, yes.

14 THE COURT: Yes.

15 A VOICE: The settlement agreement with Boehringer
16 allowed for an entry date for them to come in January 1st,
17 2010.

18 THE COURT: And what was done in exchange for that?

19 A VOICE: The -- in exchange for that we settled
20 the litigation.

21 THE COURT: Yes.

22 A VOICE: And the rest of the terms of settlement
23 are confidential.

24 THE COURT: Is there a financial payment to
25 Boehringer as part of it?

1 A VOICE: Well, that would be confidential in the
2 agreement.

3 THE COURT: But I'm the Court asking a question.

4 A VOICE: I understand.

5 THE COURT: Do you want to submit the answer in
6 camera?

7 A VOICE: Let me --

8 MS. BLOODWORTH: We would be fine with that, Your
9 Honor.

10 MR. WEXLER: Your Honor, from Mylan's perspective,
11 seeing the agreement with Boehringer also is really
12 irrelevant to any of the issues that Mylan has in this case.
13 So if Your Honor is interested in the settlement agreement,
14 that's one thing. But to give to the defendants --

15 THE COURT: I'm not saying I'm giving --

16 MS. BLOODWORTH: I just agreed to the in camera
17 review.

18 THE COURT: I said in camera.

19 You can submit it in camera, I may or may not deem
20 that I even need to look at it.

21 A VOICE: Okay.

22 THE COURT: Just submit it so we can get off of
23 that topic.

24 Okay. So Boehringer will be marketing in about six
25 months.

1 MS. BLOODWORTH: Yes, Your Honor.

2 THE COURT: When did the 30 month period of the .75
3 milligram drug start?

4 MS. BLOODWORTH: It started at approximately the
5 time this action started, so it will conclude after the
6 patent's expired. So it will -- it will run from December
7 15th, 2010, it will run into the spring of 2011, Your Honor.

8 THE COURT: What's the FDA position on whether you
9 can get final approval if there's an appeal pending?

10 MS. BLOODWORTH: We can receive final approval if
11 there is an appeal pending if this case is dismissed. If
12 there is an action here in the District Court, we cannot
13 receive final approval.

14 THE COURT: And why is that?

15 MS. BLOODWORTH: Because you cannot receive final
16 approval until there's a final decision of either invalidity
17 or non-infringement. That's the only thing that will
18 terminate a 30 month stay at this point.

19 MR. WEXLER: Your Honor, they don't -- Mylan --
20 there's one fact that hasn't been brought to light, which is
21 Mylan doesn't have a tentative approval yet. Which means
22 that even regardless of this case, the FDA hasn't approved
23 them from a scientific standpoint. So that they can't go to
24 market irrespective of this case right now.

25 THE COURT: Can -- when can they realistically expect

1 to get a scientific approval?

2 MS. BLOODWORTH: Your Honor, I can address that if
3 I may.

4 Typically, a good rule of thumb for first filed
5 applications is about a year. Mylan's has been pending
6 almost that long.

7 We do have other approved strains that are
8 tentatively approved. And I don't know how much of the
9 approval process you're aware of, but if Mylan did not have
10 the 30 month stay, we could automatically reach final
11 approval. There's no internal tentative approval situation
12 at that point. The only time you receive tentative approval
13 is if you are blocked by another applicant that is in your
14 way, there's a 30 month stay. So at this point, if this
15 case continues and Mylan's application is approved, it will
16 only receive tentative approval.

17 THE COURT: Why didn't you move to transfer to
18 Delaware where the judge knows the patent and everything
19 else?

20 MS. BLOODWORTH: Frankly, it was time. It would
21 have taken us a long time to transfer to Delaware, and then
22 we would have had to file our motion to dismiss again on the
23 same grounds we would be filing in this case here.

24 THE COURT: What -- explain to me from a litigant's
25 perspective why it takes longer to transfer.

1 MS. BLOODWORTH: We would have to file briefings,
2 I'm sure it would be opposed by plaintiffs. Correct. And
3 then Your Honor would have to approve it, and then we'd have
4 to refile in Delaware, and then we would bring a motion to
5 dismiss the Delaware action, which would then be another
6 round of briefing, and some more time and more money.

7 THE COURT: So in other words, you're saying rather
8 than -- you couldn't file a motion to transfer and then --
9 oh, I see. You're saying then it would get there and then
10 you'd have to file a motion to dismiss, so it would be
11 another briefing cycle at least.

12 MS. BLOODWORTH: Yes, Your Honor. At least, Your
13 Honor.

14 MR. WEXLER: Your Honor, in this case there's a
15 reason in the 30 month stay as far as this particular ANDA.
16 Congress didn't provide that the 30 month stay disappears
17 for this ANDA because of another ruling for a different
18 ANDA. So this ANDA gets the 30 month stay so we can resolve
19 the litigation for this particular ANDA.

20 THE COURT: Is there anything different about this
21 particular strength that's at all material?

22 MR. WEXLER: We would submit that for the purposes
23 of infringement, they stipulated to infringement in the
24 first action, that they should stipulate here that there's
25 no infringement difference with regard to the different

1 dosage strength.

2 THE COURT: Why should two different courts decide
3 this patent?

4 MS. BLOODWORTH: Well, Your Honor, that's why we
5 filed a motion to dismiss. The patent is not specific to a
6 formulation. It is specific to pramipexole. All the claims
7 for pramipexole were held invalid or were not asserted in
8 Delaware, so therefore they are precluded from being
9 asserted here today. There's nothing specific to Mylan's
10 strain .75 milligram that makes it unusual to the .125, .25
11 product.

12 MR. WEXLER: Your Honor, on the .75, Mylan was able
13 to rely on Boehringer's information of the ANDA would not
14 exempt it from the clinical data, and its data for the
15 prospective pramipexole. Mylan took advantage of
16 Hatch-Waxman and relied on their data and relied on an ANDA,
17 and Hatch-Waxman provides for the 30 month stay.

18 THE COURT: I know. Surely you've read all my
19 decisions about Hatch-Waxman going back to the dawn of time.

20 MR. WEXLER: Yes, Your Honor.

21 And Judge Debevoise in the Cima decision was based
22 on a case against Apotex and a second 30 month stay, and he
23 still granted a stay so the Patent Office could reconsider
24 the reexamination of that patent. So the 30 month stay,
25 while a factor, is not conclusive of the issue of the stay.

1 We have no tentative approval of this. And we would submit
2 that the 30 month stay --

3 THE COURT: Wait, I'm trying to understand your
4 argument a little bit. Go a little bit more slowly.

5 MR. WEXLER: Right.

6 THE COURT: What does the issue of the Patent
7 Office have to do -- is that distinguishing another case?

8 MR. WEXLER: In Cima Judge Debevoise stayed a
9 litigation, a Hatch-Waxman litigation, pending a
10 re-examination of the Patent Office of the patent.

11 So it would have been a case dispositive --
12 potentially case dispositive ruling by the Patent Office.
13 He stayed the decision. The defendant raised the 30 month
14 stay argument and Judge Debevoise weighed that fact and
15 found that judicial economy favored the stay.

16 Now, in this case we talk about the 30 month stay,
17 but what is -- what we're losing sight of is Congress didn't
18 provide that the 30 month stay disappears for this
19 particular ANDA because of what happened in another ANDA.

20 THE COURT: No, clearly the 30 month stay doesn't
21 disappear.

22 MR. WEXLER: Yes.

23 THE COURT: But how one deals with it, it's
24 certainly a factor. I mean I --

25 MR. WEXLER: And --

1 THE COURT: -- just so you understand, at the very
2 beginning of this, you know, back even before some of these
3 rules were changed, I had a Hatch-Waxman case that preceded
4 the circuit in Apotex, where everybody was running in on the
5 inducement of infringement. My first, very first, I think
6 it might have been the Organon case, I'm not a hundred
7 percent sure I remember which case it was. And everybody
8 was just taking 30 months to decide. And it occurred to me
9 that that just doesn't make sense, because there's no
10 provision in the statute for restitutional reimbursement if
11 you turn out to be wrong.

12 MR. WEXLER: And Your Honor, in this case, we have
13 the statutory framework that has the quid pro quo built in.

14 THE COURT: Correct.

15 MR. WEXLER: We have the 30 month stay here.

16 THE COURT: I totally understand the statutory
17 framework. I understand everything. The question that I'm
18 addressing, trying to understand, is issue preclusion.

19 MR. WEXLER: Now --

20 MS. BLOODWORTH: Right.

21 MR. WEXLER: -- if we --

22 THE COURT: How is it you can assert issue
23 preclusion against them in how the circuit may rule, but not
24 issue preclusion against yourself?

25 MR. WEXLER: We're not asserting issue preclusion.

1 THE COURT: You're -- in this transcript you were
2 handing up to me, there's a case saying they are issue
3 precluded. What was that argument?

4 MR. WEXLER: Your Honor, we were asked by Judge
5 Shwartz what will be -- what is the case going to look like
6 at the Federal Circuit ruling. And that's what I'm talking
7 to Your Honor about. That after the Federal Circuit ruling,
8 it's one way or the other. That either there's going to be
9 affirmance, which will end the case one way, or a reversal,
10 which if you follow Roche, what happens in Roche, a reversal
11 will result in a claim preclusion argument by us, when the
12 case is done at the Federal Circuit level.

13 Now, in Roche the District Court stayed the
14 proceedings pending the Federal Circuit review. And those
15 are the pieces of paper I gave behind there. The District
16 Court stayed the second proceedings pending Federal Circuit
17 review, and after the Federal Circuit ruled the court set up
18 a quick schedule for a dispositive motion to end the case.

19 THE COURT: The only problem I have with all that,
20 all of these stays, let this one decide, let that one
21 decide, essentially, is victory on the merits here. If
22 indeed the 30 months ends into the run end of the patent,
23 that's the problem. What looks like just a schedule issue
24 is in fact more fully on the merits, conceivably. That's
25 the concern I have. That's the reason I scheduled oral

1 argument, to speak up or forever hold your peace. Because I
2 may just rule.

3 MR. WEXLER: And I understand Your Honor is very
4 familiar --

5 THE COURT: Because it's not -- this 30 month stay
6 is a very valuable commodity. It's not just, okay, take
7 your time, let's everyone be gentle people about this.
8 That's not how this -- this is a -- a ruling on a stay
9 affects merits here, and that's the concern I have.

10 MR. WEXLER: The Congress imagined that the case
11 would be resolved within 30 months.

12 THE COURT: Congress --

13 MR. WEXLER: But this case will be resolved within
14 30 months, and the second point is, Your Honor --

15 THE COURT: But 30 months takes you to the end of
16 your patent. So they have no rights at all.

17 If you are wrong, then they -- you have blocked
18 them from selling a generic until your patent expires. That
19 is a merits decision. That's not just a timing decision.
20 That is essentially taking what could conceivably be a valid
21 cause of action and neutering it.

22 MR. WEXLER: Your Honor, the Federal Circuit
23 decision, that's October of next year.

24 And by the way, that accepts that our terminal
25 disclaimer applies, which is their argument that it doesn't

1 apply, but the terminal disclaimer we filed says the
2 expiration to that date, which is part of the appeal, which
3 is what we argue moots the double-patenting to begin with.
4 So what I'm saying is October of next year is -- the Federal
5 Circuit is going to rule before October of next year. I
6 mean we're expecting a decision October of this year.
7 October of this year. October of 2010 is when they're
8 talking about the patent expiring. We're right now only in
9 May of 2009.

10 THE COURT: Hhmm-hmm.

11 MR. WEXLER: So the median time to disposition, we
12 have argument in three weeks. The median time to
13 disposition is going to be October of this year. So they're
14 talking about another year after the median time and --

15 THE COURT: I understand.

16 MR. WEXLER: -- and if I --

17 THE COURT: Time out. Let's get back to issue
18 preclusion.

19 MS. BLOODWORTH: Yes. Yes.

20 THE COURT: I want to talk about the law.

21 MS. BLOODWORTH: Okay.

22 THE COURT: Do you have a case in which a court
23 ruled that someone was issue precluded and based on
24 something that happened at the appellate stage that issue
25 preclusion ruling was declared incorrect, overturned,

1 reversed in some way because of a disposition on appeal?

2 MR. WEXLER: We have the -- as Your Honor pointed
3 out, this area of the law is unusual.

4 But we have the case, there are two cases that
5 apply de novo exception, both issue preclusion and claim
6 preclusion applies equally in the Westinghouse case. It's
7 an old case, the PTO found that this word reduced to
8 practice the invention but suppressed it. It went up on
9 appeal to the commissioner, he upheld the suppression issue,
10 but never addressed reduction of practice. The court said
11 quote, "there's no estoppel as to reduction of practice
12 because they have, the pendency of the appeal suspends here,
13 no doubt -- this is quote, "no doubt that appeal to the
14 reviewing tribunal that hears the matter de novo suspends
15 estoppel." It's an old appeals case, but it applies to de
16 novo exception.

17 And we have the Moore case which is a District
18 Court squarely on point for issue preclusion, holding up and
19 providing it. We have --

20 THE COURT: Wasn't that a district court case
21 though where there was an actual trial de novo?

22 MR. WEXLER: No.

23 THE COURT: It was just a legal issue on appeal?

24 MR. WEXLER: Claim preclusion.

25 The first case found claim preclusion, and granted

1 summary judgment.

2 The second case, the judge refused to apply
3 collateral estoppel on the issue of claim construction,
4 because the claim construction was up on appeal at the
5 Federal Circuit.

6 It's on all fours with the idea of a de novo review
7 of the legal issue. And Wright and Miller says it's a
8 grotesque result to premise a dismissal, a substantive
9 dismissal on a ruling that's currently on appeal in this
10 case, and I understand Your Honor's position, but here it's
11 de novo review, that means without deference --

12 THE COURT: That's what I said --

13 MR. WEXLER: The Delaware Judge said that there's a
14 good record on both sides, and that the real answer is going
15 to come in Washington.

16 So we -- and I understand Your Honor's, that -- and
17 I'm fully familiar with de novo review, but we get de novo
18 review without deference, it's so grotesque a result to
19 permit a dismissal --

20 THE COURT: How about issue preclusion here,
21 without prejudice to your right to present the issue to the
22 Delaware Judge immediately if there's reversal in the
23 Federal Circuit?

24 MS. BLOODWORTH: Your Honor, before we move --

25 MR. WEXLER: Your Honor --

1 MS. BLOODWORTH: Can I please address Mr. Wexler's
2 points --

3 THE COURT: Yes.

4 MS. BLOODWORTH: -- which are, first of all,
5 completely confusing the issues of de novo review with a
6 full trial de novo.

7 The Federal Circuit in 2000 specifically ruled, and
8 I'm going to read the Pharmacia v. Mylan case, the quote,
9 "the law is well-settled that the pendency of an appeal has
10 no effect on the finality or binding effect of a trial
11 court's holding."

12 It is black letter law that they are precluded from
13 asserting this patent against Mylan right now. They may not
14 like that result. They may hope that the record proves to
15 be in their favor in the future. They have other remedies
16 maybe then at that time they can take.

17 But the fact is right now they are precluded from
18 arguing this. It's well-settled law it's not an exception.
19 It's in a Southern District of Ohio unpublished decision --

20 THE COURT: If -- if you said the Federal Circuit
21 ruled two hours ago and reversed the Delaware decision two
22 hours ago, you're waiting for oral argument, so now you know
23 that it's been reversed.

24 MS. BLOODWORTH: Yes, Your Honor.

25 THE COURT: Same arguments on issue preclusion,

1 exactly the same arguments?

2 MS. BLOODWORTH: Yes, Your Honor. Exactly the
3 same.

4 Except for -- except at that point the Delaware
5 court would have to know the entry decision would come back
6 down and the Delaware court would go on the books as
7 reversed and, obviously, as Mr. Wexler argued in his papers,
8 he will be arguing about preclusion on the other side.
9 That's the impact of the finality of the judgment.

10 Right now the Delaware court entered final
11 judgment. The 812 patent is invalid. The Pharmacia case is
12 the de novo review of the obviousness determination of the
13 court's decision below.

14 MR. WEXLER: Your Honor, I really would recommend
15 that Your Honor please review Pharmacia and the appeal.
16 Because it's a misstatement that the review in that case was
17 de novo. It was an obviousness determination, an
18 unenforcability finding. The appeal was fact sensitive, and
19 if you look at the Upjohn v. Mobil case, they denied, 225
20 Fed. 1306, you'll see that the appeal was heavily fact
21 intensive. They cite the Merck decision and state that
22 obviousness is de novo. Merck on the next page says, quote,
23 "obviousness is an issue of law based on underlying fact
24 determinations reviewed for clear error." Pharmacia
25 involved a case where the appeal was heavily fact intensive,

1 first of all. Second of all, the appeal hadn't even been
2 filed in Pharmacia. As was alluded to, down the road months
3 from now they were going to file a JMOL. So the JMOL would
4 come months later, the appeal would come in that case, the
5 court refused to -- I mean the court applied collateral
6 estoppel, went up on appeal, there was no discussion of the
7 de novo issue because it wasn't de novo review.

8 MS. BLOODWORTH: Your Honor, that's exactly the
9 point. The point is that the court affirmed a District
10 Court's dismissal or entry of collateral estoppel despite
11 the fact that a JMOL was still pending in the movants
12 decision, and despite the fact that it had then been
13 appealed during the collateral estoppel finding, so --

14 THE COURT: I'm going to ask you both one last
15 chance to describe this to me. And my hypothetical is, the
16 Federal Circuit ruled two hours ago and reversed the
17 District Court in Delaware. Now, how, if at all, are the
18 issue preclusion arguments raised in your brief changed?

19 MR. WEXLER: Your Honor, so --

20 THE COURT: Wait a minute I'm addressing it to her,
21 then you'll have your chance.

22 MR. WEXLER: I'm sorry.

23 THE COURT: All right.

24 MS. BLOODWORTH: Your Honor, we would argue that
25 until the actual order in the District Court was changed,

1 that final District Court order was changed, there would be
2 no impact to this case standing here today. And to get to
3 your question, even if what the court concluded in Pharmacia
4 was quote, if another panel later concludes that one or more
5 of the juried verdicts in Pharmacia should be reopened,
6 Upjohn may then move the District Court to modify its
7 judgment accordingly. They have relief that's available to
8 them other than prosecuting an action that's full of just
9 speculative claims at this point of the case.

10 THE COURT: What would be their relief?

11 MS. BLOODWORTH: They could file --

12 THE COURT: Let's suppose I were to grant your
13 motion.

14 MS. BLOODWORTH: Yes, Your Honor.

15 THE COURT: And then tomorrow, tomorrow the Federal
16 Circuit reverses the Delaware District Judge. What's their
17 relief?

18 MS. BLOODWORTH: First of all, I think probably
19 they would seek relief in Delaware.

20 But second of all, they could always file a Rule
21 60(b) request.

22 THE COURT: Well, they'd seek relief in Delaware of
23 the Delaware judgment. The Delaware court wouldn't have
24 jurisdiction over this judgment.

25 MS. BLOODWORTH: We've all agreed to venue in

1 Delaware, regardless. The Delaware court could come and
2 wrap up all the ANDAs in one case in front of Judge Farren
3 at one time.

4 MR. WEXLER: Judge, this is different. Again, the
5 Federal Circuit would be within -- if we're going to have a
6 Federal Circuit reversal, we're going to have to reopen the
7 judgment, we're going to have an appeal on the collateral
8 estoppel issues, we're going to be briefing the issue of
9 whether this court properly applied collateral estoppel.

10 THE COURT: You can do that.

11 MR. WEXLER: All I'm saying, in terms of judicial
12 economy, we're now burdening the Federal Circuit with
13 another appeal. If either the Federal Circuit reverses on
14 the collateral estoppel or underlying decision gets
15 reversed, we're back here trying to reopen the judgment at
16 that --

17 THE COURT: No, you're in Delaware. Trying -- the
18 presumptive premise is that at some later time the Delaware
19 court gets reversed and you've transferred it there.

20 MR. WEXLER: The agreement was that we stay the
21 case, the Federal Circuit reverses, do we transfer to
22 Delaware, not this court dismisses and then we --

23 THE COURT: Excuse me. I've already made it very
24 clear, and I appreciate your worry about judicial economy
25 for the Federal Circuit. I'm also worried about judicial

1 economy for the District Court and the Magistrate Judge and
2 judicial economy is judicial economy, doesn't matter which
3 court it is.

4 MR. WEXLER: And we're suggesting, Your Honor, to
5 write an opinion on collateral estoppel, on a debated issue
6 --

7 THE COURT: Are you willing to enter an agreement
8 that financially recompenses them for the period of time, if
9 I were to go with your argument for some settlement, for a
10 financial way of establishing what it is that you're
11 concerned about economy with, maybe today we can forge an
12 agreement about how many dollars you pay them to have
13 everybody just sit still and wait for the Federal Circuit.

14 MR. WEXLER: I mean I don't even -- I guess I could
15 think about how that would play out.

16 THE COURT: Well, do you want to take a short break
17 to do that? I'm happy to go off the bench, I have some --
18 seriously, maybe there's some kind of way the two of you can
19 work something out. A stay is not just preserving the
20 status quo. A stay is a win for you. Under the way the
21 Hatch-Waxman statute is used today.

22 MR. WEXLER: It's --

23 THE COURT: And therefore, I'm saying if you really
24 want to just preserve the status quo, avoid burdening
25 judicial economy, which I'm all in favor of, I mean avoid

1 burdening courts, then work something out that makes it
2 really fair to do so.

3 MR. WEXLER: Your Honor, they don't have tentative
4 approval now. So it's unclear what we're even --

5 THE COURT: If you don't want to work something
6 out, you don't have to work something out.

7 What I'm saying is, let me get off the bench, why
8 don't you take 20, 30 minutes, discuss it with each other,
9 maybe when you're not under the pressure of answering a
10 court's questions there might be some creative way that you
11 can together work out a structure that is fair to one and
12 all while the circuit is considering the Delaware case.
13 That -- I mean maybe there isn't, maybe there is. I have no
14 idea.

15 MR. WEXLER: Yes. I just -- I'm happy to talk
16 about it. Seems unfair when we have the right that attaches
17 to this particular ANDA and a quid pro quo --

18 THE COURT: You don't have the stronger part of the
19 argument on issue preclusion.

20 MS. BLOODWORTH: And Hatch-Waxman did not mean to
21 supplant issue preclusion.

22 MR. WEXLER: And --

23 THE COURT: You don't have the -- I'm not saying
24 how I'm going to rule. You don't have the stronger argument
25 on --

1 MR. WEXLER: It's an open issue on issue
2 preclusion.

3 THE COURT: I recognize it is. And you're saying
4 basically, don't rule on it, we don't have to appeal, which
5 frankly, you have a right to, that's just fine.

6 But it would be one thing if it was just preserving
7 the status quo. But it's giving you what you want
8 substantively as well. And therefore, it is in a sense a
9 mini-ruling on the merits.

10 MR. WEXLER: But the status --

11 THE COURT: And unless -- the concern I have,
12 fairness, it's just about fairness.

13 MR. WEXLER: Your Honor, the status quo in a
14 Hatch-Waxman case contemplates the presence of a 30 month
15 stay until the litigation is resolved on the merits. And
16 what we're saying is that --

17 THE COURT: If you're saying that, that's fine.
18 But then there will be no stay.

19 So if you want a stay, work something out with each
20 other.

21 MS. BLOODWORTH: And, Your Honor, may I give your
22 clerk the Pharmacia case?

23 THE COURT: Yes, you may.

24 I'm not saying there will be no 30. The 30 month
25 stay goes until I rule. But I'm just not going to sit here.

1 MR. WEXLER: I'm sorry, Your Honor, may we give you
2 the Upjohn --

3 THE COURT: Yes, you may.

4 (After a brief recess court resumed).

5 THE CLERK: All rise.

6 THE COURT: You may all be seated.

7 Is there any agreement of any kind reached to
8 render it unnecessary to continue?

9 MR. WEXLER: Your Honor, we couldn't come up with a
10 proposal that would be fair and we asked Mylan and Mylan --

11 THE COURT: No idea?

12 MR. WEXLER: -- had no idea either, so --

13 THE COURT: Okay. Fair enough.

14 MR. WEXLER: One other thing we had raised briefly
15 was this concept that if the Federal Circuit were to reverse
16 and this case were to be dismissed, and Mylan hypothetically
17 in their scenario does launch, then we have to rush back to
18 the Court to reopen the judgment, file a preliminary
19 injunction and seek damages. So that would be the structure
20 of the case at that moment.

21 THE COURT: They would be launching at risk, I
22 suppose, is what you're saying, to whatever you might or
23 might not get by way of relief.

24 MR. WEXLER: Once the Federal Circuit reverses and
25 the patent -- yes, once the Federal Circuit reverses and the

1 patent is held valid, then we would have to come back to
2 this court, because this court premised its decision on the
3 reverse of the collateral estoppel, a decision that has been
4 reversed. We would have to come back, reopen a judgment,
5 seek an injunction, emergency injunction and damages. I
6 proposed hypothetically would they be willing to stipulate,
7 in that case they would be willing to stipulate to the
8 injunction and damages if the Federal Circuit reversed.
9 Obviously, we didn't reach agreement on that.

10 THE COURT: But you're both trying to figure out
11 -- that's what I thought you might be able to work out
12 together. Because you've got the benefit of a 30 month stay
13 right now on a patent that's been held invalid. And you're
14 holding them off the market on a patent that's invalid right
15 now.

16 And they have the issue of whether or not what
17 would be the sequellae if the circuit were to reverse. So
18 both of you have a degree of uncertainty about your
19 positions, which is why I thought you might be able to forge
20 something, being brilliant creative legal minds. That was
21 the thought in my mind.

22 MR. WEXLER: And, Your Honor, I think the 30 month
23 stay contemplates the difficulty of that situation
24 because --

25 THE COURT: Actually, the 30 month stay really

1 couldn't. This is a rather unique circumstance. I know
2 you're a wonderful advocate, but trust me, I've read
3 everything there is to read about this and that stay, and
4 this isn't what they were thinking --

5 MR. WEXLER: Thank you, Your Honor.

6 THE COURT: -- they are balancing various rights
7 and opportunities, as well they should, and that's their job
8 and they're congress, and our job is to enforce their law
9 and that's what we did.

10 MR. WEXLER: But the 30 month stay wasn't
11 dissipated or waived on a different ANDA filing, so the 30
12 month stay is specific to the ANDA, to litigate it on the
13 merits and that is the only reason I --

14 THE COURT: But it is accusing them of infringing a
15 patent which right now is invalid.

16 MS. BLOODWORTH: Yes, Your Honor.

17 MR. WEXLER: And in our final judgment, Your Honor,
18 we have a de novo review of the issues that are on appeal.
19 And one other thing --

20 THE COURT: I understand your position.

21 Let me ask you, why doesn't a lot of the language
22 in the Roche case that you gave to me come back to bite you?

23 MR. WEXLER: Because, if Your Honor looks at the
24 next, the next piece of paper that I gave you, in the Roche
25 case the -- in the Roche case, if you look at the dates on

1 page 1376, Your Honor will see that the Federal Circuit
2 affirmance was in 2007. It was April 2007. So the Federal
3 Circuit affirmed the first judgment in April 2007. And the
4 District Court then didn't hear summary judgment until after
5 that.

6 THE COURT: Wait. I'm not following you. You're
7 saying --

8 MR. WEXLER: Oh --

9 THE COURT: -- which page are you referring me to?

10 MR. WEXLER: If Your Honor, I'll --

11 THE COURT: No, just tell me. Which --

12 MR. WEXLER: Okay. The page 1376 of the Federal
13 Circuit's opinion --

14 THE COURT: Right.

15 MR. WEXLER: -- and if we look at the first
16 column, the last sentence of the first column. It's the
17 first full paragraph on 1376.

18 THE COURT: Yes.

19 MR. WEXLER: If -- you'll see there's a reference
20 there to, and we affirm without opinion, 2007. So -- and
21 that is, that's discussing the first action, and there was
22 an affirmance of the first action in -- and it was April
23 2007. The Lexis one will show the date, it was April 2007.

24 Now, if we continue through the opinion and we --
25 and we look at the second column, where they talk about the

1 District Court's summary judgment motion, we see that was
2 September 11, 2007. So it was many, many months after the
3 Federal Circuit's affirmance on appeal.

4 Now, I saw those dates and I pulled the underlying
5 District Court ruling. And those two pieces of paper I
6 showed you, I gave you, if Your Honor still has them.
7 Document 37 states, this case has been stayed while the
8 validity of the patent was litigated in this court and the
9 Federal Circuit. So in other words, the procedural posture
10 of this case was that there was a District Court finding,
11 there was an appeal, the District Court stayed the
12 proceedings pending the Federal Circuit appeal. The moment
13 the Federal Circuit ruled, the parties got together for a
14 status conference, and we can see that in the first piece of
15 paper I gave you, document number 37. And so they came to
16 the court right after the Federal Circuit ruling, they told
17 the Federal Circuit about the affirmance. And then in the
18 next piece of paper I gave you, 48, the --

19 THE COURT: But they affirmed the decision that the
20 patent was not invalid, so they upheld the patent.

21 MR. WEXLER: They upheld the patent. So the stay,
22 the patent was still valid while the stay was in effect.

23 THE COURT: The problem, the concern I have about
24 fairness here --

25 MR. WEXLER: Yes.

1 THE COURT: -- is the fairness of continuing a stay
2 based on a patent that's been held invalid. And my other
3 concern, the corollary concern, is fairness of issue
4 preclusion, if there should be a reversal. And so those are
5 the two fairness concepts that I'm trying to balance in what
6 I do.

7 MR. WEXLER: And I appreciate.

8 MS. BLOODWORTH: And Your Honor --

9 MR. WEXLER: If I may just address those two
10 points.

11 The first is that, and I appreciate that this is a
12 difficult situation we're in. And the first thing --

13 THE COURT: Which is why I thought that you might
14 have a little more flexibility in trying to work something
15 out.

16 MR. WEXLER: The problem, Your Honor, is that for
17 us to agree to pay them pending a decision by the Federal
18 Circuit raises a host of issues that are, number one,
19 complicated; and number two, you know, a transfer of money
20 to them is not something we would do lightly.

21 THE COURT: I'm not saying anybody should do
22 anything lightly. I just thought that you might have tried
23 to -- both sides might have been able to quickly, maybe not
24 so quickly, to work out something that made sense in this
25 posture.

1 MR. WEXLER: In the half an hour that we had we
2 couldn't think of something that would be satisfactory and
3 they weren't able think of something that satisfied --

4 THE COURT: Clearly. Which is fine.

5 MR. WEXLER: Now, one thing, as an alternative, is
6 the question of this stay.

7 Judge Shwartz set up a schedule, and I don't know
8 if Your Honor has a copy, but we have a copy now. But the
9 structure of the schedule that the parties agreed to, it
10 hasn't been entered yet by Judge Shwartz, so I apologize if
11 I suggest that she entered it.

12 But the way, the structure of the schedule now is
13 basically we do contention, we just identify our contentions
14 through the period of about October, November. So no real
15 heavy lifting on any discovery issues. We identify our
16 contentions.

17 And then next year, at the beginning of the year,
18 we can start in with any discovery. But presumably by then
19 the Federal Circuit will have ruled.

20 So the structure of the schedule right now postures
21 this case so that we will get a Federal Circuit ruling at a
22 time when we know contentions of the parties and that would
23 be a lot like the Roche case, where if we win, the Roche
24 case kicks in, where the court, as I mentioned, stayed
25 proceedings once the Federal Circuit --

1 THE COURT: But in Roche they won, the patent was
2 held valid. Right? Now you're on the opposite side of
3 that --

4 MR. WEXLER: But they stayed --

5 THE COURT: -- the patent is invalid. They stayed
6 with a valid patent. So the 30 months seemed fair to the
7 judge who had that case. The judge who had that case said
8 this patent's valid, so it seems fair to continue this.

9 MR. WEXLER: Two things. I'm not citing that case
10 for the 30 month stay principle.

11 The principle of that case is they stayed the case
12 pending the Federal Circuit, so that there was -- they
13 didn't apply collateral estoppel in that case to the
14 defendant. Because if the Federal Circuit reversed, then
15 they would have been reopening the judgment and premising a
16 judgment on a decision that's been reversed.

17 I cited the Cima case where Judge Debevoise issued
18 a stay in a Hatch-Waxman case, and he weighed the 30 month
19 issues in that case, but they were a fact --

20 THE COURT: I understand that. But when I started
21 doing Hatch-Waxman work a long time ago, judges were
22 routinely taking the entire amount of time to decide these
23 cases, and it occurred to me that that was wrong. That we
24 should proceed with a little greater but deliberate speed.
25 And I still took 12 months to decide a case that I should

1 have been able to decide in three months. But I still took
2 12 months because the decision I initially came down with in
3 my first Organon decision was so novel at the time, no one
4 had come down with it yet, and so I thought, well, why does
5 this seem so novel? I don't know.

6 So I took my time and I thought it through an
7 entire summer, and finally rendered a ruling in about 12
8 months, which struck me as a long time. And thought, you
9 know, all the timbers were rattling, it was such a terrible
10 thing to do, six weeks later the circuit came down with the
11 exact same decision, albeit in another case. So there
12 really wasn't a need to have gone through so much Sturm and
13 Drang to do it. But we did.

14 MR. WEXLER: And Your Honor, in this case where the
15 parties have proposed a schedule, and I would submit, Your
16 Honor, there's no greed in this case, as if you look at the
17 schedule we proposed, it actually wraps up before even the
18 end of the 30 month stay. I have as example, it ends the
19 pretrial conference in the September time frame --

20 THE COURT: Just understand what I'm thinking
21 about. I'm back to what I told you I thought. I'm striving
22 for fairness, fairness here. So something that's fair to
23 both sides. That's what I'm trying to see how to do.
24 Because both sides have legal principles that have an
25 element of fairness underlying them. They have an argument

1 that they can't, even if they could get approval, they can't
2 get final approval, they can't go to market because the suit
3 is pending based on a patent that's been found invalid by
4 the court in Delaware. That's their argument as to why it's
5 unfair to them.

6 Your argument as to why it's unfair to you is you
7 you don't want to be thrown completely out of court in the
8 event that the Federal Circuit overrules the finding of the
9 court of Delaware that found the patent invalid.

10 Those are the two competing fairness concepts that
11 I'm working towards a resolution of.

12 MR. WEXLER: And Your Honor --

13 THE COURT: Let me ask you this. So your argument
14 as to why -- let me ask you, why are you not citing Roche
15 Palo Alto versus Apotex?

16 MS. BLOODWORTH: Because we agree that it's
17 distinguishable. As a matter of fact, we were counsel in
18 that case for Allergan.

19 THE COURT: And why is it distinguishable?

20 MS. BLOODWORTH: It's distinguishable because there
21 was no patent that was held invalid during the case, there's
22 no collateral estoppel preclusion effect that took place on
23 the side of the patentee in the Roche v. Allergan case.

24 THE COURT: But what about the alternate holding
25 that Judge Prost discusses starting at page -- hang on a

1 second, starting at Roman numeral IV of that case.

2 MS. BLOODWORTH: Yes, Your Honor. And I see in
3 Roman numeral IV, if you, you know, the case is again
4 factually distinguishable and I, again, don't -- and I
5 believe this is Mr. Wexler's point, if the case had been
6 affirmed on appeal already --

7 THE COURT: It had already been affirmed.

8 MS. BLOODWORTH: Yes.

9 And what plaintiffs -- what's the difference here
10 is that the finality of the judgment is not in question of
11 the District Court. Plaintiffs are trying to use the
12 fairness exception to say that the Delaware District Court's
13 judgment isn't final. The fact is we're harmed by this
14 stay, and by the filing of this action, like Your Honor
15 said, and thank you for that.

16 But the other, the flip side of it is if that
17 speculation, if the Federal Circuit reverses, and if Mylan
18 is launched in the meantime, the remedy to Boehringer is
19 damages, is monetary. They don't have any harm. They've
20 already agreed to your position --

21 THE COURT: What I have to -- okay. So what --
22 what would be the normal route? Let's suppose I were to
23 agree with you on issue preclusion and the Federal Circuit
24 reverses.

25 MS. BLOODWORTH: Yes, Your Honor.

1 THE COURT: Then what is fair, what are
2 Boehringer's options fairly to do?

3 MS. BLOODWORTH: Boehringer's option at that point
4 would be the same option that any other patent holder had in
5 any patent infringement case. They can bring a suit if
6 Mylan has launched for an injunction, for damages and/or
7 they can bring an action in Delaware to have the .75 ANDA
8 action assumed in the judgment, in the reversal judgment.

9 THE COURT: What does it mean to say to have it
10 assumed in?

11 MS. BLOODWORTH: If we agree to transfer the case.

12 THE COURT: Yes, you're going to Delaware no matter
13 what. I'm searching for fairness.

14 MS. BLOODWORTH: Yes.

15 And so in fairness what they have, they're in no
16 different position if Mylan hasn't launched, with or without
17 the stay -- with or without the stay. Whether this case is
18 dismissed or not, Mylan hasn't launched. They're in the
19 same place.

20 If Mylan has launched, then they have the right to
21 potentially get money damages and monetary damages aren't
22 harm. They can be compensated for whatever loss they may
23 have. And they have already agreed to generic competition.
24 Mylan is not going to be the only person selling a .75
25 milligram generic gramusol, the tablet, this would be a

1 patent case like any other patent which runs its typical
2 route while there's a product in the marketing. It's taking
3 product, market share in the product on the market and the
4 patentee goes into the court and gets an injunction and asks
5 for monetary damages.

6 MR. WEXLER: So Your Honor, under this
7 hypothetical, what, if the court dismisses, what they're
8 suggesting, we have to come back to this court --

9 THE COURT: Not in this Court. You're going to
10 Delaware.

11 MR. WEXLER: Well, I mean if this suit is filed in
12 this court, and the court dismisses under their
13 hypothetical --

14 THE COURT: What I'm considering, and I'll take
15 both of your comments on this, is a dismissal and transfer.
16 Okay? Dismissal, and in the alternative, transfer.

17 And the dismissal of that is without prejudice to
18 your -- to the right of Boehringer, if the Federal Circuit
19 overrules the District Court in Delaware, to petition the
20 court in Delaware for any appropriate relief based on
21 anything in the Federal Circuit's ruling that they deem
22 appropriate to seek appropriate relief from Delaware on.
23 That's the concept I'm thinking about.

24 MR. WEXLER: So under that concept then we would be
25 appealing the Court's dismissal to the Federal Circuit.

1 THE COURT: You can do whatever you want.

2 MR. WEXLER: I'm just asking how it would play --

3 THE COURT: I'm not sure how you can appeal. It's
4 a dismissal without prejudice, so you'll have to decide
5 whether you can appeal or not under those circumstances.

6 MR. WEXLER: So in terms of the ramification --
7 see, again, if we don't appeal we have the grotesque result
8 of a final judgment of dismissal.

9 THE COURT: You can appeal -- I don't know whether
10 they'll take your appeal under those circumstances. Because
11 if I were they, I would say, well, if we were to reverse,
12 then they have the right to go to the Delaware District
13 Court and seek any appropriate relief there in the first
14 instance. Why don't we, the Federal Circuit, wait and see
15 what the Delaware court does with respect to that. But they
16 could decide, I mean I'm just saying that's what I would do.

17 MR. WEXLER: The --

18 MS. BLOODWORTH: And Your Honor --

19 MR. WEXLER: -- as Wright and Miller explains in
20 their treatise --

21 THE COURT: I know, you say that's grotesque.

22 MR. WEXLER: I'm -- no, I'm saying they posit that
23 in a complex settlement, where you don't -- dismissal of the
24 collateral estoppel, and you forfeit your rights to the
25 challenge and the collateral estoppel, even if the judgment

1 is so, we would have to file an appeal to protect our
2 rights.

3 THE COURT: You can file anything you want.
4 Obviously. So I'm just saying whatever, you can file
5 whatever you want.

6 MR. WEXLER: So --

7 THE COURT: I'm just asking you, both of you,
8 that's the scenario, I've come up with as a way to be as
9 fair as possible to both sides in this matter.

10 MR. WEXLER: Yes, Your Honor --

11 MS. BLOODWORTH: And, Your Honor, if I may, in
12 answer to Mr. Wexler, Mr. Wexler addressed the question of
13 whether Hatch-Waxman would require a final judgment --

14 THE COURT: Final judgment --

15 MS. BLOODWORTH: -- so if your order was to
16 dismiss based upon colateral or res judicata --

17 THE COURT: Isn't dismissal without prejudice a
18 final judgment?

19 MS. BLOODWORTH: Yes, Your Honor. That would be
20 our argument for sure. We would definitely argue that would
21 be final. We would be before the FDA most likely on that.
22 But again, that would be okay with us.

23 But really, the point here is that while Mr. -- you
24 know, while Boehringer's group has the right to go into
25 Delaware and get a remedy, Mylan doesn't have any remedy.

1 If this case is not dismissed, we don't have any remedy. We
2 will be precluded from getting FDA approval by this action.
3 We don't have any monetary damages that we can resort to.
4 No one would be able to -- you know, is obligated to
5 compensate Mylan in any way. For -- we would essentially
6 have defended the same patent twice in two different courts,
7 and that's the very point and purpose of Rule 12.

8 And as for their concern -- and again, if I can
9 back up a little bit to some of the points we were
10 discussing with Mr. Wexler, one of the key things that this
11 motion to stay is requesting is really an abbreviation or a
12 hypothetical, you know, sort of a suspension of the finality
13 of the Delaware judgment, and that's exactly what the
14 Federal Circuit denied in the Pharmacia case, which was
15 another Hatch-Waxman case, and they said, and I quote from
16 page 13 -- 1301, "Upjohn next argues that the District Court
17 should have stayed the proceedings pending the resolution of
18 its motion in Mobil" --

19 THE COURT: I'm still finding the page.

20 MS. BLOODWORTH: Sure. It's in page 9 of the
21 WestLaw printout.

22 THE COURT: Yes. I'm there.

23 MS. BLOODWORTH: The first full paragraph on the
24 right hand column.

25 THE COURT: Got it.

1 MS. BLOODWORTH: And it says, "Upjohn next argues
2 the District Court should have stayed the proceedings
3 pending a resolution of its motion," and then it goes on,
4 "furthermore they requested consolidation of these
5 arguments. Upjohn in effect disputes the finality of the
6 Mobile judgment and essentially the compensability of its
7 applicability for collateral estoppel purposes. We disagree
8 with Upjohn's arguments." These very arguments that are
9 being made here today on collateral estoppel and their
10 motion to stay. It's on all fours with what the Federal
11 Circuit already held in the Pharmacia case.

12 THE COURT: Well, it talks about possible appeal in
13 that.

14 MS. BLOODWORTH: And that case was still on
15 judgment as a matter of law. So the District Court judgment
16 was a jury verdict. But then they had filed post-trial
17 motions on it, and those post-trial motions at the time that
18 the Northern District -- at the time of the Pharmacia court,
19 District Court entered judgment, the post-trial motions were
20 still pending.

21 MR. WEXLER: But Your Honor --

22 MS. BLOODWORTH: So the very point is that this is
23 even -- this goes to, is even more applicable here, and the
24 court goes on to explain this. Where the finality, where
25 the judgment then goes up on appeal. What they held was an

1 even broader rule of collateral estoppel, is that the final
2 judgment is final despite the pendency of the post-trial
3 motions and despite the fact of appeal.

4 MR. WEXLER: Your Honor --

5 THE COURT: Mr. Wexler, you'll have your chance --

6 MS. BLOODWORTH: So the Cima case was a case that
7 didn't involve issue preclusion. State doesn't --

8 THE COURT: And the Cima case is another District
9 Court --

10 MS. BLOODWORTH: -- but the Federal Court here
11 addressed if there is an earlier decision that finds a
12 patent invalid for obviousness is it precluded, and they
13 said yes.

14 THE COURT: What is the significance then in the
15 very last Supreme Court quote in the Roche case that says,
16 that refers to an unappealed judgment?

17 In the very last page, page 1381 of Roche Palo Alto
18 versus Apotex they quote, as the Supreme Court explained,
19 quote, "Nor are the res judicata consequences of a final
20 unappealed judgment on the merits altered by the fact -- by
21 the fact that the judgment may have been wrong or rested on
22 a legal principle subsequently overruled in another --

23 MS. BLOODWORTH: That's a different -- they're
24 talking about how the SPR --

25 THE COURT: I understand that. But what is the

1 significance of using the word, unappealed, in that court,
2 out of the Federated Department Store case?

3 MS. BLOODWORTH: I think what they're saying is in
4 that case there was no appeal to the judgment, it wasn't an
5 appealable judgment. And in Pharmacia the judgment was
6 appealable --

7 THE COURT: So -- so we have an appeal pending
8 situation?

9 MS. BLOODWORTH: Which is what was happening in
10 Pharmacia. Correct.

11 THE COURT: I understand.

12 MR. WEXLER: No --

13 THE COURT: Excuse me, Mr. Wexler, what did you
14 want to say?

15 MR. WEXLER: I'm saying in Pharmacia it wasn't
16 pending. You emphasized the word possible appeal, so it's
17 incorrect to say the appeal was pending.

18 MS. BLOODWORTH: It's actually not. Because while
19 this was being decided, the parties did appeal the case.
20 And if you look at page, the bottom of page 10, the bottom
21 right-hand side, the court actually points to the fact that
22 it was harmful that the collateral estoppel decision was
23 correct, and it was properly due, because if it hadn't, if
24 you hadn't collaterally estopped the parties, they would
25 have -- the ANDA filing would have then had to be waiting

1 for -- to receive final approval in the abbreviated drug
2 application until that case, the earlier case that received
3 a final decision, a final appealable decision. And the
4 court, especially, the court specifically held that is not
5 proper. The fact of an appeal, the appeal does not have any
6 effect on res judicata. It doesn't have an effect on the
7 finality of the judgment.

8 MR. WEXLER: Your Honor, if I may respond.

9 THE COURT: But if what -- but if there were to be
10 a reversal at the Federal Circuit, which then resulted in a
11 the Delaware -- on whatever ground, it could be, and no
12 point speculating, and the Delaware court as a result of
13 that were to change its judgment, then conceivably even
14 Judge -- even in the Roche versus Apotex case they talk
15 about the fact that there could be some rare exception, some
16 momentous change in important fundamental constitutional
17 rights is the quote that comes out of that case. Maybe it's
18 not even constitutional. That there could be important
19 fundamental rights that could be affected in this unusual
20 circumstance, which is why I'm searching for what's fair.
21 And it seems that what's fair is to allow -- is to
22 essentially transfer it, to the extent there are any further
23 proceedings in this case, transfer to Delaware with the
24 right to petition the court in Delaware for any appropriate
25 relief that they believe is just and proper following the

1 Federal Circuit's decision in the appeal of the District of
2 Delaware case.

3 MS. BLOODWORTH: And that's why Mylan would be okay
4 with the transfer.

5 MR. WEXLER: Your Honor --

6 THE COURT: All right.

7 Or agree this 30 month stay doesn't, you know, gets
8 suspended. That's what I was seeing if you two, if you
9 wanted to enter into some kind of agreement where perhaps
10 you would be relieved of the -- or you know, there could be
11 some exchange of rights in this interim period, since you
12 both face potential issues. He faces the issue that you may
13 market, you may face the issue you may market under jeopardy
14 that you may be sued for damages if that patent was
15 overruled. You both have downsides. So do you want to take
16 sometime and try to see if you can hash out some kind of
17 fair compromise here?

18 MR. WEXLER: And Your Honor --

19 THE COURT: That recognizes the fairness to both?

20 MS. BLOODWORTH: And again, the problem is we don't
21 have any remedy other than -- I mean we only have the remedy
22 of asking this court to dismiss this action. You know,
23 aside from your -- the scenario you just laid out, we don't
24 have any right to go after Boehringer for money damages if
25 we don't work out an agreement. Boehringer always has the

1 right to come after Mylan for damages if we ever launch a
2 product under duress. If --

3 MR. WEXLER: Your Honor, -- I'm sorry.

4 THE COURT: Go ahead, Mr. Wexler.

5 MR. WEXLER: No, in terms of looking at this from
6 fairness, that situation where you're describing that the
7 case is dismissed, Mylan can launch, we have an appeal
8 pending with de novo review. First, if there's a reversal,
9 we go and attack the judgment that was premised on a
10 collateral estoppel, non-final judgment for the purposes of
11 appeal, and then we have to go --

12 THE COURT: It is a final judgment.

13 MR. WEXLER: Not for the purposes of appeal. I
14 mean --

15 THE COURT: It's a final judgment of a court.

16 MR. WEXLER: But it isn't final in the sense of,
17 for example, would the -- in other words, is it done -- you
18 know, as the appeals court is reviewing this --

19 THE COURT: Right.

20 MR. WEXLER: -- we all agree there's an exception.
21 Now the contours of that exception are not well-defined.

22 THE COURT: Right.

23 MR. WEXLER: But there's a reason that exception
24 exists, and the reason it exists is when you have a de novo
25 review it's --

1 THE COURT: No, that's not the exception I'm
2 talking about. The exception that's referred to in the case
3 you gave me, the Roche versus Apotex case, was talking about
4 a rare exception in cases involving quote, "momentous
5 changes in important fundamental constitutional rights,"
6 unquote. That's the kind of -- they're not talking about
7 what you're talking about. They're talking about a --

8 MR. WEXLER: Roche --

9 THE COURT: -- in fact, if you look at Judge
10 Prost's long, I think it's Judge Prost. Yes. She says in,
11 basically halfway through the second column on page 1380,
12 "the District Court however correctly recognized that there
13 is no change of law or fairness exception to prevent
14 application of a claim for claim preclusion," and then she
15 quotes Federated Department Stores, quote, "for us to
16 conclude under the facts of this case that the District
17 Court's order has become an instrument of wrong merely
18 because it rests on a since repudiated rational would be to
19 nullify the doctrine of res judicata under," quote, and then
20 she quotes a Fifth Circuit case, then she quotes an Eleventh
21 Circuit case, that basically say the general rule throughout
22 the nation is changes in the law after a final judgment do
23 not prevent the application of res judicata and collateral
24 estoppel, even though the ground on which the decision was
25 based were subsequently overruled.

1 MR. WEXLER: Right.

2 THE COURT: So -- but it's talking about being
3 overruled in another case, and I understand this. The
4 distinction that I see, that's novel in what we're dealing
5 with, is that it is in the Delaware case which rests on the
6 the very same patent that is presently under appeal, but to
7 give you 30 month stay benefits for a patent that's right
8 now an invalid patent has fairness issues for the other
9 side.

10 MR. WEXLER: And we're not asking for Your Honor to
11 simply establish a 30 month stay, we're going to sit back
12 and let it go in terms of the timing of this case right
13 now --

14 THE COURT: I'm saying -- you're not hearing, Mr.
15 Wexler.

16 MR. WEXLER: I understand.

17 THE COURT: You're an advocate. You need to
18 listen --

19 MR. WEXLER: I'm listening.

20 THE COURT: -- and be a little creative. Do you
21 want a little time to be creative? I'll give it to you.

22 MR. WEXLER: Yes, Your Honor, we would.

23 THE COURT: Good. Why don't you try to be a little
24 creative.

25 MR. WEXLER: Okay.

1 THE COURT: That's what I would do, if I were you.

2 MR. WEXLER: Okay.

3 THE COURT: All right.

4 Try to work something out. I'll take a little
5 recess.

6 THE CLERK: All rise.

7 (After a brief recess court resumed).

8 THE CLERK: All rise.

9 THE COURT: You may all be seated.

10 All right. Here's my ruling.

11 This action is dismissed on grounds of issue and/or
12 claim preclusion as a result of the Delaware District
13 Court's final judgment in Boehringer Ingelheim, etcetera,
14 versus Mylan Labs, Inc., invalidating the 812 patent. The
15 Court recognizes that the Delaware District Court's decision
16 is presently on appeal to the Federal Circuit. If the
17 Federal Circuit were to reverse the final judgment of patent
18 invalidity, the instant dismissal is without prejudice to
19 Boehringer's right to seek all appropriate injunctive and/or
20 monetary relief against Mylan in enforcement of its patent
21 rights. Moreover, if the Federal Circuit were to reverse
22 the District Court in the Boehringer versus Mylan Labs case,
23 the instant dismissal is without prejudice to Boehringer's
24 right to seek any other appropriate relief from the effects
25 of issue preclusion, if it can demonstrate a rare exception

1 to that principle to the satisfaction of the Delaware
2 District Court.

3 By agreement of the parties, if there are any such
4 further proceedings in this case after a decision is issued
5 by the Federal Circuit, this case is hereby transferred to
6 the District of Delaware, with the recommendation that it be
7 assigned to and/or coordinated with the prior action in that
8 district regarding the same patent.

9 The Court recognizes the request for a stay pending
10 the Federal Circuit's decision, but finds that fundamental
11 fairness is better served by the outcome now reached. While
12 Boehringer will have significant rights to sue for an
13 injunction and damages if the Federal Circuit were to
14 reverse the Delaware District Court's finding of patent
15 invalidity, the converse situation of continuing a 30 month
16 stay in support of a patent that has been declared invalid
17 is without any legal recourse for Mylan. Therefore, the
18 balance of the equities favors the instant result.

19 I will give the court reporter the official name of
20 the Delaware case that I said "etcetera" in the first line,
21 so that he has it. You can order it from him if you wish
22 it.

23 Is there anything further I can do for you?

24 MR. WEXLER: No, Your Honor.

25 MS. BLOODWORTH: No, Your Honor. Thank you.

1 THE COURT: Okay.

2 Thank you, counsel.

3 EXTRA ATTORNEY: Thank you, Your Honor.

4 THE CLERK: All rise.

5 THE COURT: Oh. You can share these.

6 MS. BLOODWORTH: Thank you, Your Honor.

7 THE COURT: It's okay.

8 (Court adjourned).

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